

### REMARKS

The Office Action objected to Figure 1 and the specification. Applicants will amend the drawings and specification upon a finding of allowable subject matter.

The Office Action set forth the following rejections:

claims 1-5 were rejected under 35 U.S.C. § 101 and § 112, first paragraph, as lacking utility; and

claims 4 and 5 were rejected under 35 U.S.C § 112, first paragraph, as not being enabled.

With respect to the Section 101 and 112 rejections of the claims as lacking utility, as stated before the present application leaves no doubt that the CAPN11 sequence is expressed most strongly in testis (see present application, page 2, last paragraph and Figure 3). It also established that CAPN11 is involved in processes like germ cell apoptosis or regulation of testis-specific transcription factors (see present application, page 3, last paragraph). Moreover, CAPN11 can be used as a bait for identifying substances which are able to inhibit the enzymatic activity of the polypeptide (see present application, page 4, lines 1-21). Such inhibitors, in turn, can be used for the treatment of disorders associated with or linked to a non-physiologically elevated CAPN11 activity such as infertility in men (see present application, page 4, lines 23-26). The Office Action concludes that these techniques are not specific enough to establish utility. Applicants assert that one of skill in the art would have no doubt as to the utility of the claimed subject matter in view of these teachings.

As noted in the previous Amendment Ben-Aharon et al., 2006 clarifies that the expression of calpain-11 during spermatogenesis and its localization in spermatozoa suggest that it is involved in regulating calcium-dependent signal transduction events during meiosis and sperm functional processes. To one of skill in the art, this clearly indicates that CAPN11 is involved in spermatogenesis which further supports the conclusions drawn in the present application, i.e. that tinkering with CAPN11-activity by using either CAPN11 or the corresponding

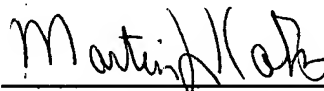
inhibitor is useful in treating diseases associated with an unphysiological increased CAPN11 activity or infertility in men. In view of the above, the objection should have been rendered moot. For the above-noted reasons, these rejections are improper and should be withdrawn.

With respect to the Section 112, second paragraph, rejection, claims 1-5 have been amended as suggested by the Examiner. Therefore, this rejection should be withdrawn.

With respect to the written description rejection, the Office Action rejected claims 4 and 5 as containing subject matter which was not described in the specification in a way as to reasonably convey to a skilled worker that the inventors at the time of the application was filed had possession of the claimed invention. Allegedly, the specification does not teach the methods as defined in claims 4 and 5 directed to a method for identifying modulators of the activity of the polypeptides set forth by SEQ ID NO: 2. Applicants respectfully disagree. In this respect, the Examiner's attention is again directed to page 4 of the application which leaves no doubt that the enzyme activity of CAPN11 is a Ca-dependent protease activity. This would clearly lead one of skill in the art to conclude that a method for identifying an inhibitor of the particular protein is taught. Thus, a skilled worker would have clearly concluded that the invention as defined in claims 4 and 5 complies with the written description requirement and this rejection should be withdrawn.

Favorable consideration of claims 1-5 as presently amended is respectfully requested.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this Amendment and associated papers are being deposited with the United States Postal Service with sufficient postage at First Class Mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on **April 12, 2007**.

Rachel Burke